K070308

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Flexlens Multifocal Soft Contact Lens
(hioxifilcon A) and (hioxifilcon B)

MAR 12 2007

I. Submitter Information

510(k) Owner: X-Cel Contacts
2775 Premiere Parkway, Suite 600
Duluth, GA 30097

Contact Person: Robert Chambers
(770) 622-9235

USA Consultant: Kevin Randall
GlobalReg Compliance Associates, Inc.
581 Whiles Court
Erie, CO 80516
(303) 956-8595 (direct)
(303) 828-0835 (fax)
Email: kevin@globalregcompliance.com

Date Summary Prepared: January 30, 2007

II. Name of Device

- Trade Name: Flexlens Multifocal Soft Contact Lens (hioxifilcon A) and (hioxifilcon B) for Daily Wear
- Common Name: Daily Wear Soft Contact Lens
- Classification Name: Lenses, Soft Contact, Daily Wear
- USAN (generic name): (hioxifilcon A) and (hioxifilcon B)

III. Predicate Devices

Subject Device	Predicate Device(s)
Flexlens Multifocal Soft Contact Lens (**hioxifilcon A**)	Proclear Ultravue Multifocal (**K043129**)
	Horizon 59 Oasis (hioxifilcon A) Progressive (**K043540**)
Flexlens Multifocal Soft Contact Lens (**hioxifilcon B**)	ESSTECH MULTI Aspheric (multifocal) (hioxifilcon B) Soft Contact Lens (**K982904**)

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Flexlens Multifocal Soft Contact Lens
(hioxifilcon A) and (hioxifilcon B)

IV. Device Description & Technological Characteristics

The Flexlens Multifocal Soft Contact Lens (hioxifilcon A) and (hioxifilcon B) for Daily Wear is indicated for daily wear use for the correction of refractive ametropia (myopia, hyperopia and/or presbyopia) in non-aphakic persons.

The non-ionic lens material, **hioxifilcon A**, is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydrosypropyl Methacrylate (Glycerol Methacrylate, GMA). It consists of 41% hioxifilcon A and 59% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. Flexlens Multifocal Soft Contact Lenses for Daily Wear made out of hioxifilcon A are available in clear and with a blue visibility-handling tint, phthalocyanato (2) – (copper).

The physical properties of the **hioxifilcon A** lens are:

Refractive Index	1.404 (hydrated)
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	59 %
Specific Gravity	1.18 (hydrated)
Oxygen Permeability	18×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

The non-ionic lens material, **hioxifilcon B**, is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2,3-Dihydrosypropyl Methacrylate (Glycerol Methacrylate, GMA). It consists of 52% hioxifilcon B and 48% water by weight when immersed in normal saline solution buffered with sodium bicarbonate. Flexlens Multifocal Soft Contact Lenses for Daily Wear made out of hioxifilcon B are available in clear and with a blue visibility-handling tint, phthalocyanato (2) – (copper).

The physical properties of the **hioxifilcon B** lens are:

Refractive Index	1.404 (hydrated)
Light Transmission (clear)	greater than 95% T
Light Transmission (tinted)	greater than 95% T
Water Content	48 %
Specific Gravity	1.136 (hydrated)
Oxygen Permeability	15×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg @ 35°C), (revised Fatt method).

The Flexlens Multifocal Soft Contact Lens (hioxifilcon A) and (hioxifilcon B) for Daily Wear is a lathe-cut soft lens multifocal with an aspheric front surface and a spherical base curve. In the dry (unhydrated) state the lens is machined and polished. The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution. The progressive optics utilize the simultaneous vision concept which offers functional vision from distance to near throughout the viewing range. The pupil zone on the front surface varies with the size of the patient's pupil.

V. Intended Use

The Flexlens Multifocal Soft Contact Lens (hioxifilcon A) and (hioxifilcon B) for Daily Wear is indicated for daily wear use for the correction of refractive ametropia (myopia, hyperopia and/or presbyopia) in non-aphakic persons.

VI. Pre-Clinical Performance Data

Pre-clinical performance data can be referenced for hioxifilcon A and hioxifilcon B in Benz Research and Development's 510(k) # K983773 and # K964528.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 2007

X-Cel Contacts
c/o Mr. Kevin Randall
581 Whiles Court
Erie, CO 80516

Re: K070308
Trade/Device Name: Flexlens Multifocal Soft Contact Lens (hioxifilcon A) and (hioxifilcon B) for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: II
Product Code: LPL
Dated: February 26, 2007
Received: February 26, 2007

Dear Mr. Randall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070308

Device Name: Flexlens Multifocal Soft Contact Lens (hioxifilcon A) and (hioxifilcon B) for Daily Wear

Indications For Use:

The Flexlens Multifocal Soft Contact Lens (hioxifilcon A) and (hioxifilcon B) for Daily Wear is indicated for daily wear use for the correction of refractive ametropia (myopia, hyperopia and/or presbyopia) in non-aphakic persons

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marc Rolby

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K070308